

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION

04 Civ. 9866 (RO)

**DEFENDANTS' NOTICE OF ADDITIONAL AUTHORITY IN SUPPORT OF THEIR
OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE**

Defendants Pfizer Inc. (“Pfizer”) and Dr. Henry A. McKinnell, Dr. John L. LaMattina, Karen L. Katen, Joseph M. Feczko, M.D. and Gail Cawkwell, M.D. (the “Individual Defendants,” collectively, “Defendants”) respectfully submit this Notice of Additional Authority in Support of their Opposition to Plaintiffs’ Motion to Strike Certain Exhibits Attached to the Declaration of Gregory A. Markel and Related Portions of the Memorandum of Law in Support of Defendants’ Motion to Dismiss the Complaint.

Defendants submit this Notice to bring to the Court’s attention two decisions: In re Intrabiotics Pharmaceuticals, Inc. Securities Litigation, No. C 04-02675- JSW, 2006 WL 708594 (N.D. Cal. Jan. 23, 2006) and Noble Asset Management v. Allos Therapeutics, Inc., No. CIVA-04CV-1030-RPM, 2005 WL 4161977 (D. Colo. Oct. 20, 2005). These decisions are attached, respectively, as Exhibits A and B. They further support the argument set forth by Defendants in their Sur-Reply Memorandum of Law in Opposition to Plaintiffs’ Reply Memorandum of Law in Further Support of their Motion to Strike (“Sur-Reply”) that this Court should consider Exhibit 45 to the Supplemental Declaration of Gregory Markel dated August 2, 2006. Exhibit 45 is the FDA’s Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products dated May 1998 (“FDA May 1998 Guidance for Industry”), an FDA document available on the FDA’s website. See Sur-Reply at 3-4. We note that Plaintiffs did not move to strike any of the other FDA documents available on the FDA’s website that Defendants submitted in support of their Motion to Dismiss.

Intrabiotics Pharmaceuticals and Noble Asset Management support this Court’s consideration of the FDA’s May 1998 Guidance for Industry because they both considered other Guidance for Industry documents published by the FDA in ruling on and dismissing Section 10(b) claims. In Intrabiotics, a case alleging federal securities claims relating to, among other things, the disclosure of the results of a clinical study, the court granted the defendants’ request that it take judicial notice of “the FDA’s document entitled Guidance for Industry” in ruling on defendants’ motion to dismiss, finding that the document was a proper subject for judicial notice. Intrabiotics, 2006 WL 708594, at *8. Similarly, in Noble Asset Management, which involved allegations that

the defendants violated Section 10(b) by misrepresenting the prospects for FDA approval of the drug at issue, the court denied the plaintiffs' motion to strike an FDA document entitled "Guidance for Industry E9 Statistical Principles for Clinical Trials" that the defendants submitted with their motion to dismiss. The court found that the document could be considered because it was a "public document[] provided by the FDA relating to its process for reviewing new drug applications and that process [was] central to an evaluation of the claims made in this case." Noble Asset Management, 2005 WL 4161977, at *2.¹ Like the FDA's Guidance for Industry that the courts considered in ruling on the motions to dismiss in Intrabiotics and Noble Management, the Court should consider the FDA's May 1998 Guidance for Industry attached as Exhibit 45 to the Supplemental Market Declaration. As explained in Defendants' Sur-Reply, this document should be considered because it is an FDA document that is publicly available on the FDA's website and that describes the term statistical significance, which is used, but not defined, in the Second Circuit's decisions in the Carter-Wallace cases. See Sur-Reply at 3-4; In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36 (2d Cir. 2000); In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153 (2d Cir. 1998).

¹ The courts in these cases also dismissed the Section 10(b) claims against the defendant pharmaceutical manufacturers. See Intrabiotics, 2006 WL 708594, at *12 (plaintiffs failed to allege sufficient facts to show that the defendants made a materially false or misleading statement); Noble Asset Mgmt., 2005 WL 416977, at *12-13 (plaintiffs' allegations were insufficient to show that defendants made a false or misleading statement or give rise to a strong inference that the defendants knew that the drug would not be approved).

Dated: New York, New York
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